FORM PTO-1390 U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER
ETH1404

U S APPLICATION NO (If known, see 37 CFR 1.5)
10/070219

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/04817	May 26, 2000	August 31, 1999

TITLE OF INVENTION
REINFORCED AREAL IMPLANT

APPLICANT(S) FOR DO/EO/US :
Barbara Schuldt-Hempe, Rosenstr. 23, D-24576 Bad Bramstedt and Christoph Walther, Dorfstr. 35, D-24568 Kattendorf

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.

2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.

3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).

4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).

6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.

8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).

9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. ☐ A translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☐ Other items or information:

JC13 Rec'd PCT/PTO 26 FEB 2002

U.S. APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
10/070219	PCT/EP00/04817	ETH1404

17. ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):	CALCULATIONS PTO USE ONLY	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO.....$1040.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO.....$890.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.455(a)(2)) paid to USPTO..... $740.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)..... $750.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)..... $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 1040.	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	11 - 20 =		x $18.00	$ 198.	
Independent claims	1 - 20 =		x $84.00	$ 84.	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $280.00	$ 280.	
TOTAL OF ABOVE CALCULATIONS =				$ 1602.	
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).			+	$	
SUBTOTAL =				$	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)) .				$	
TOTAL NATIONAL FEE =				$ 1602.	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$	
TOTAL FEES ENCLOSED =				$	
				Amount to be refunded:	$
				charged:	$1602.

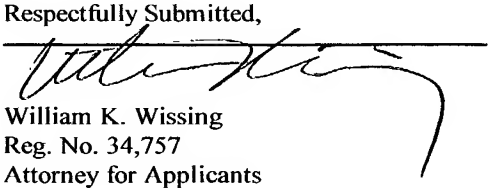
a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 10-0750/ETH1404/WKW in the amount of $1602. to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 10-0750/ETH1404/WKW. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

Respectfully Submitted,



William K. Wissing
Reg. No. 34,757
Attorney for Applicants

SEND ALL CORRESPONDENCE TO:

Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003 USA
Dated: February 26, 2002

3/prts

Reinforced Areal Implant

The invention concerns a reinforced areal implant, which can be used particularly for the repair of inguinal hernias.

From U.S. Patent 2 671 444, a net-type surgical implant for the treatment of hernias is known. This implant is manufactured from polyethylene and can be cut to the required size by a surgeon. One disadvantage is that the implant is relatively stiff.

In order to improve the cloth-like quality of an implant net made from polypropylene or polyester for the treatment of hernias, it is proposed in DE 295 11 411 U1 to arrange attachments to the implant net, which are at least partially absorbable and which adhere to anatomical structures.

Furthermore, there are available implant nets made of polypropylene mono-filament which have a relatively great areal weight (implant mass) of 100 g/m^2 and a pore size of less than 1 mm. These implants nets are very stiff. Therefore, they are good for a laporoscopic application, as they unfold without difficulty, for example, but they do not match anatomical conditions in an optimal way. Thus, a cavity is readily formed,

if these implants are used for the repair of inguinal hernias. Further disadvantages are the formation of a thick, strong scar plate and a disturbance of abdominal wall movement. Moreover, it is hard to see through such implant nets, which makes operations more difficult.

Conventional implant nets knitted from a composite material having an absorbable and a non-absorbable constituent are less stiff. Warp and pillar stitch are made of multi-filament yarns from non-absorbable polypropylene and an absorbable copolymer of L-lactide and glycolide in the ratio 10:90, which is marketed by the applicant under the designation "Vicryl". The areal weight amounts to about 56 g/m^2 with a polypropylene part of about 25 g/m^2. These implant nets fit the anatomical conditions well; they are soft and flexible and form no folds or cavities. Only a weak scar formation comes about, and the abdominal wall movement is not seriously disturbed. A pore size of about 2-4 mm provides good transparency. The reduced stiffness, however, brings disadvantages. For example, handling during care of an inguinal hernia is made more difficult. Such implant nets are ill-suited for laporoscopic use, as they are hard to unfold. In particular, a partial fold-out of the implant net against the spermatic cord can lead to problems.

The object of the invention is to provide an areal implant particularly suitable for repairing an inguinal hernia which on the one hand offers a good fit to anatomical conditions, but on

the other hand is easily handled and can also be used for laporoscopic applications.

This problem is solved by a reinforced areal implant with the features of Claim 1. Advantageous versions of the invention emerge from the sub-claims.

The reinforced areal implant according to the invention has a net-type basic structure with a pore size in the range 1.5 mm to 4.0 mm. It comprises textile strengthening elements whose bending resistance is in the range 0.015 N/mm to 0.4 N/mm. The bending resistance is given here with numerical values which can be determined in a three-point flexibility test in which the bending in the middle of a textile strengthening element is measured as a function of the force acting onto the middle of the textile strengthening element and perpendicularly to the textile strengthening element, where the (free) support length of the textile strengthening element is 20 mm. The numerical value given for the bending resistance in N/mm arises from the slope of this experimental curve in the region of smaller forces or bendings, where largely linear conditions dominate.

The net-type basic structure, at a pore size of 1.5 mm to 4.0 mm, is relatively coarse-mesh so that good transparency to the underlying tissue is possible, which facilitates surgery. The relatively large pores of the net-type basic structure also permit the entire implant mass being held low. The areal weight

of the reinforced areal implants accoeding to the invention is preferably in the range 50 g/m^2 to 150 g/m^2. If the implant mass is low, after the surgery there are less foreign-matter reactions, and the implant heals in well, which again is assisted by the relatively large pores. On the other hand, the pores are sufficiently small for the net-type basic structure to accomplish the required support and holding function in the area of the surgery.

The textile strengthening elements have the effect that the reinforced areal implant according to the invention, as a whole, has an adèquate stiffness for handling. It can therefore be well used in inguinal hernia repairs and also in laparoscopic applications. For example, the edges of the implant do not fold out, if the implant, starting at one of its edges, is cut, in order to lay it round the spermatic cord. On the other hand, the implant is not too stiff so that it fits to the anatomical conditions without folds or cavity formation and also does not essentially disturb the movability of the abdominal wall.

Preferably, the strengthening elements form a net-type strengthening structure with a pore size from 5 mm to 30 mm, this pore size preferably being several times the pore size of the basic structure. Such a coarse-mesh arrangement of the strengthening elements is sufficient to provide a sufficient stiffness of the implant.

In a preferred embodiment, the basic structure of the implant comprises a knitted fabric. Preferably, the strengthening elements are laid or knitted into the basic structure. In this case, the implant can be produced as a whole through a mesh-forming process. A possibility is the production with the aid of the multi-bar technology on crochet galloon machines or raschel machines.

Preferably, the basic structure comprises non-absorbable material (e.g. multi-filament yarn of polypropylene) or very slowly absorbed material (i.e. material that 180 days after the surgery still has at least 50% of its initial tear-strength), e.g. in a contribution with an areal weight in the range of 10 g/m^2 to 50 g/m^2. As this material is not absorbed or only slowly absorbed, the basic structure can assume the desired supporting and holding function in the patient's body permanently or at least for a very long period of time.

It is particularly advantageous, if additionally the basic structure has absorbable multi-filament yarn. For example, yarns of poly-p-dioxanone or yarns of a copolymer of L-lactide and glycolide (especially in the ratio 10:90, i.e. "Vicryl", or in the ratio 95:5) or mixtures of such yarns or multi-filament yarns are suitable. The absorbable yarns in the basic structure have the effect that the implant fits particularly well to local anatomical conditions and shows no folds or cavity formation on application. It is particularly helpful if a relatively large

part of "Vicryl" multi-filament yarns is used. Fine "Vicryl" yarns are very quickly moistened by body fluids and therefore adhere to soft body tissue like fascia, muscles or the peritoneum much better than fabric structures from polypropylene multi-filament yarns or mono-filaments, which are very hydrophobic. With the aid of absorbable multi-filament yarns in the basic structure, it is thus possible for the implant in the operating area to fit very well and to attach to tissue, although it is relatively stiff as a whole, so as to improve handling.

For the strengthening elements, in particular pure mono-filaments, twisted mono-filaments, twisted or composite multi-filament yarns or mixtures thereof are suitable. The strengthening elements can be non-absorbable, partly absorbable, or completely absorbable. Suitable for strengthening elements are, for example, mono-filaments of polypropylene, multi-filament yarns of polypropylene, mono-filaments of poly-p-dioxanone, multi-filament yarns of a copolymer of L-lactide and glycolide in the ratio 10:90 ("Vicryl"), yarns of poly-p-dioxanone or mixtures thereof.

In a preferred embodiment of the invention, at least part of the strengthening elements has a color different from that of the basic structure. In this way, it is possible to provide the implant with a coarse-mesh colored grid, which makes it easier to a surgeon during surgery to assess any distortion of the

implant. Preferably the color remains temporary only, i.e. after the surgery it fades. If the strengthening elements have several components, e.g., a mono-filament part or a multi-filament part of the strengthening elements can be colored.

Preferably, an implant provided for a surgical operation will be cut to size from areal material beforehand. But it is possible to use pre-made-up implants, for which, if required, the edge region can be secured against unravelling or reinforced. For the treatment of inguinal hernias, implants can be advantageous which have an aperture for the spermatic cord.

In the following, the invention is described more precisely by means of examples. The figures show in

Figure 1 a schematic representation of the knitting pattern of a first embodiment of the reinforced areal implant according to the invention,

Figure 2 a schematic representation of the knitting pattern of a second embodiment of the reinforced areal implant according to the invention, and

Figure 3 a schematic representation of the knitting pattern of a third embodiment of the reinforced areal implant according to the invention.

In the figures 1 to 3 the model patterns (paper notation of patterns) and mesh layout of three embodiments of reinforced areal implants are represented schematically in a way familiar to the expert. The implants according to these three embodiments have a basic structure, into which strengthening elements (model shoot III, model shoot IV) are inserted.

Table 1 Thread system and material in the three embodiments according to model I, model II und model III

No.	Thread System	Material
I	Warp: open pillar stitch	1 x 60 den PP twine
	Model shoot I+II: Basic knitting construction Rapport across 6 loops	Twist of 4 x 80 den "Vicryl" + 1 x 60 den PP
	Model shoot III+IV: Pattern structure Rapport across 24 loops	Twist variant H Twist of 4 x 60 den PP, 2 x 80 den "Vicryl", violet and 1 x 6 mil PP mono-filament 1 x 4 fold twist + mono-filament
II	Warp: open pillar stitch	1 x 60 den PP twine
	Model shoot I+II: Basic knitting construction Rapport across 6 loops	Twist of 4 x 80 den "Vicryl" + 1 x 60 den PP
	Model shoot III+IV: Pattern structure Rapport across 36 loops	Twist variant D Twist of 2 x 80 den "Vicryl", violet, and 4 x 60 den PP
III	Warp: open pillar stitch	1 x 60 den PP twine
	Model shoot I+II: Basic knitting construction Rapport aross 6 loops	Twist of 4 x 80 den "Vicryl" + 1 x 60 den PP

Model shoot III+IV: Pattern structure Rapport across 24 loops	Twist variant I Twist of 4 x 60 den PP, 2 x 80 den "Vicryl", violet and 1 x 6 mil PP mono-filament 1 x 7 fold twist

---

1 mil = 0.0254 mm; 1 den = 1 Denier

Further data for the thread systems and data concerning the material and kind of the yarns and filaments used are listed in Table 1 for these three embodiments. The strengthening elements "twist variant H" (model I), "twist variant D" (model II), and "twist variant I" (model III) are explained further below in more detail. In the case of all three embodiments, both the basic structure and the strengthening elements comprise absorbable and non-absorbable material, namely polypropylene (PP) as non-absorbable material and a copolymer of L-lactide and glycolide in the ratio 10:90 ("Vicryl") as absorbable material.

There follow some embodiments of strengthening elements which can be used in a reinforced areal implant. In the examples, in a way familiar to the expert, the materials and construction of the strengthening elements as well as their diameter and bending resistance are given. The latter is measured in a three-point flexibility test at a support length of 20 mm, as explained further above.

Example A

Material:	Mixture of poly(vinylidene fluoride) and poly((vinylidene fluoride)-co-hexafluoropropylene)
Structure:	Mono-filament
Diameter:	0.247 mm
Bending resist.:	0.243 N/mm

Example B

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)
Structure:	6 x 60 den PP and 2 x 80 den "Vicryl"; twist
Diameter:	0.428 mm
Bending resist.:	0.023 N/mm

Example C

Material:	PP mono-filament (thickness 6 mil) and violet "Vicryl" multi-filament yarn (80 den)
Structure:	3 x 6 mil mono-filament and 2 x 80 den "Vicryl", violet
Diameter:	0.328 mm
Bending resist.:	0.147 N/mm

Example D

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)
Structure:	4 x 60 den PP and 2 x 80 den "Vicryl", violet
Diameter:	0.294 mm
Bending resist.:	0.017 N/mm

Example E

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)
Structure:	6 x 60 den PP yarn and 2 x 80 den "Vicryl" yarn as two-step twist: 1st step 1254 T/m, S-twist; 2nd step 465 T/m, Z-twist
Diameter:	0.407 mm
Bending resist.:	0.031 N/mm

Example F

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)
Structure:	6 x 60 den PP yarn and 2 x 80 den "Vicryl" yarn as two-step twist: 1st step 1769 T/m, S-twist; 2nd step 695 T/m, Z-twist
Diameter:	0.338 mm
Bending resist.:	0.021 N/mm

Example G

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den); plus PP mono-filament yarn
Structure:	4 x 60 den PP yarn and 2 x 80 den "Vicryl" yarn and 1 x 6 mil-PP mono-filament als two-step twist: 1st step 1112 T/m, S-twist; 2nd step 413 T/m, Z-twist (1 x 7 twist)
Diameter:	0.307 mm
Bending resist.:	0.103 N/mm

Example H

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den); plus PP mono-filament yarn
Structure:	4 x 60 den PP yarn, 2 x 80 den "Vicryl" yarn, violet, and 1 x 6 mil-PP mono-filament as two-step twist: 1st step 1112 T/m, S-twist; 2nd step 413 T/m, Z-twist; yarns shrunk in multiple-wound manner (4 + 1 twist)
Diameter:	0.395 mm
Bending resist.:	0.14 N/mm

Example I

Material:	PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den); plus PP mono-filament yarn
Structure:	4 x 60 den PP yarn, 4 x 80 den "Vicryl" yarn, violet and 1 x 6 mil-PP mono-filament as two-step twist: 1st step 1112 T/m, S-twist; 2nd step 413 T/m, Z-twist; yarns shrunk in multiple-wound manner (4 + 1 twist)
Diameter:	0.37 mm
Bending resist.:	0.1 N/mm

The abbreviation PP, as well as the name "Vicryl" were already explained earlier. 1 mil = 0.0254 mm; 1 den = 1 Denier.

Amended Claims

1. Reinforced areal implant, comprising
   - a net-type basic structure having a pore size in the range 1.5 mm to 4.0 mm and
   - textile strengthening elements whose bending resistance, measured in a three-point flexibility test at a support length of 20 mm, is in the range 0.015 N/mm to 0.4 N/mm, wherein the strengthening elements form a net-type strengthening structure with a pore size in the range 5 mm to 30 mm.

2. Implant according to claim 1, characterized in that the pore size of the strengthening structure is a multiple of the pore size of the basic structure.

3. Implant according to claim 1 or 2, characterized in that the basic structure comprises knitware.

4. Implant according to claim 3, characterized in that the strengthening elements are laid or knitted into the basic structure.

5. Implant according to one of claims 1 to 4, characterized in that the basic structure comprises non-absorbable material or very slowly absorbable material that retains at least 50% of its initial tear-strength after 180 days in-vivo.

6. Implant according to claim 5, characterized in that the basic structure comprises multi-filament yarn made of polypropylene.

7. Implant according to one of claims 1 to 6, characterized in that the basic structure comprises absorbable multi-filament yarn.

8. Implant according to one of claims 1 to 7, characterized in that the basic structure has at least one of the components selected from the following group: yarn of poly-p-dioxanone, yarn of a copolymer of L-lactide and glycolide in the ratio 10:90, yarn of a copolymer of L-lactide and glycolide in the ratio 95:5, yarn of a copolymer of L-lactide and glycolide in a different ratio.

9. Implant according to one of claims 1 to 8, characterized in that the strengthening elements comprise at least one of the components selected from the following group: pure mono-filaments, twisted mono-filaments, twisted multi-filament yarns, composite multi-filament yarns.

10. Implant according to claim 9, characterized in that the strengthening elements comprise at least one of the components selected from the following group: mono-filaments of polypropylene, multi-filament yarns of polypropylene, mono-filaments of poly-p-dioxanone, multi-filament yarns of

a copolymer of L-lactide and glycolide in the ratio 10:90, yarns of poly-p-dioxanone.

11. Implant according to one of claims 1 to 10, characterized in that at least part of the strengthening elements has a color different from that of the basic structure.

Abstract -

A reinforced areal implant particularly suitable to the repair of inguinal hernias has a net-type basic structure with a pore size of 1.5 mm to 4.0 mm and comprises textile strengthening elements, whose bending resistance, measured in a three-point flexibility test at a support length of 20 mm, is in the range 0.015 N/mm to 0.4 N/mm. The basic structure preferably contains a non-absorbable material and additionally an absorbable multi-filament yarn.

Model I

Warp: open pillar stitch
Bar3: model shoot I
Bar4: model shoot II
Bar5: model shoot III
Bar6: model shoot IV

Model pattern:

Warp	Bar3	Bar4	Bar5	Bar6
2	2	4	12	0
0	6	0	8	4
0	2	4	10	2
2	4	2	6	6
	0	6	6	6
	4	2	8	4
			4	8
			4	8
			6	6
			2	10
			2	10
			4	8
			0	12
			4	8
			2	10
			2	10
			6	6
			4	8
			4	8
			8	4
			6	6
			6	6
			10	2
			8	4

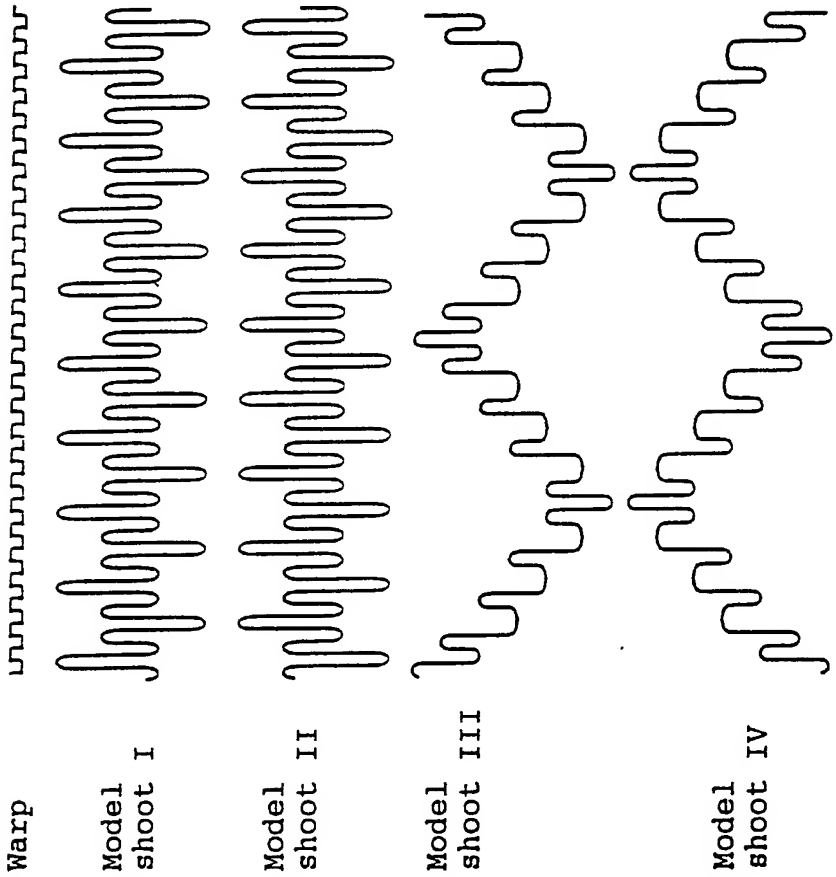


Fig. 1

Model II

Warp: open pillar stitch
Bar3: model shoot I
Bar4: model shoot II
Bar5: model shoot III
Bar6: model shoot IV

Model pattern:

Warp	Bar3	Bar4	Bar5	Bar6
2	2	4	16	0
0	6	0	12	4
0	2	4	14	2
2	4	2	10	6
	0	6	10	6
	4	2	12	4
			8	8
			8	8
			10	6
			6	10
			6	10
			8	8
			4	12
			4	12
			6	10
			2	14
			2	14
			4	12
			0	16
			4	12
			2	14
			2	14
			6	10
			4	12
			4	12
			8	8
			6	10
			6	10
			10	6
			8	8
			8	8
			12	4
			10	6
			10	6
			14	2
			12	4

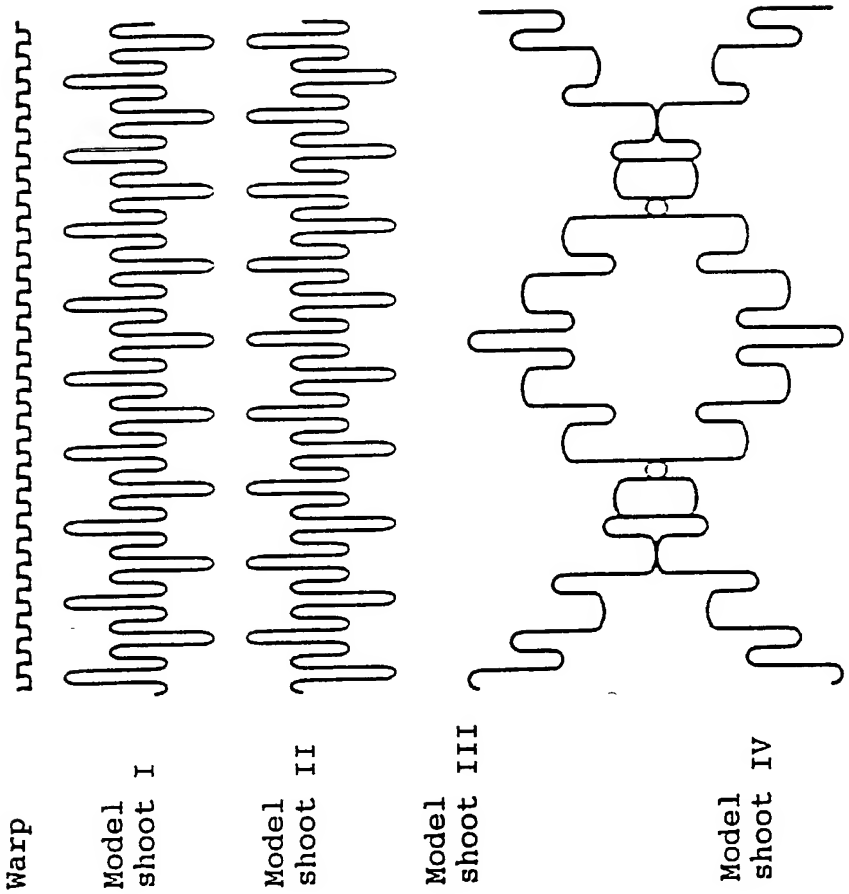


Fig. 2

Model III

Warp: open pillar stitch
Bar3: model shoot I
Bar4: model shoot II
Bar5: model shoot III
Bar6: model shoot IV

Model pattern:

Warp	Bar3	Bar4	Bar5	Bar6
2	0	4	18	0
0	2	10	16	2
0	0	8	18	0
2	6	10	12	6
	4	4	14	4
	6	6	12	6
			8	10
			10	8
			8	8
			4	4
			6	6
			4	4
			0	0
			2	2
			0	0
			6	6
			4	4
			6	6
			10	10
			8	8
			10	10
			14	14
			12	12
			14	14

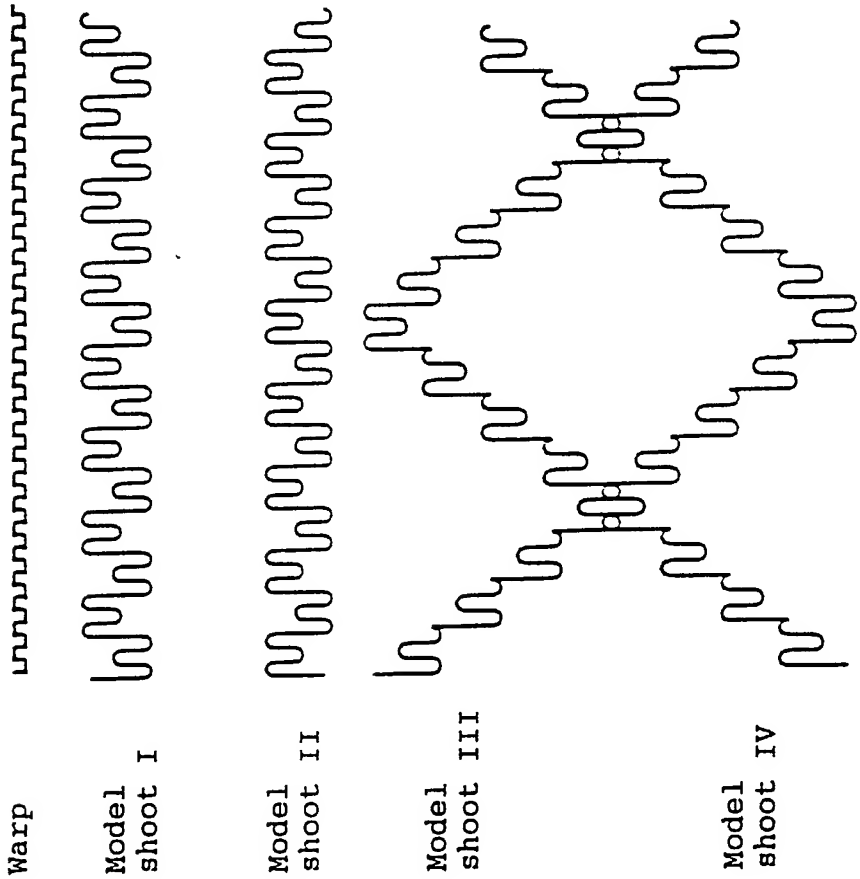


Fig. 3

P51173

Please type a plus sign (+) inside this box [+]

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office, U S DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing **OR** ☒ Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required)

Attorney Docket Number	ETH1404
First Named Inventor	Barbara Schuldt-Hempe, et al
COMPLETE IF KNOWN	
Application Number	10/070,219
Filing Date	February 26, 2002
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

REINFORCED AREAL IMPLANT
(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
199 42 611.2	Germany	08/31/1999	☐	☐	☒
PCT/EP00/04817		05/26/2000	☐	☐	☒
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
		Patented Patented Patented

I hereby appoint:

☒ Practitioners at Customer Number **000027777** →

AND

☐ Practitioner(s) named below:

Name Registration Number

Place Customer Number Bar Code Label Here

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Address all telephone calls to William K. Wissing at telephone number (732) 524-6201.

Direct all correspondence to: ☒ Customer Number or Bar Code Label **000027777** OR ☐ Correspondence address below

Name:		
Address:		
Address:		
City:	**State:**	**ZIP**
Country	**Telephone:**	**Fax:**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Barbara	**Family Name or Surname** Schuldt-Hempe
Inventor's Signature B. Schuldt - Hempe	**Date** 22.03.02
Residence: City Rosenstr DEX **State**	**Country** Germany **Citizenship** Germany
Mailing Address Rosenstr. 23, D-24576 Bad Bramstedt	
City Rosenstr **State**	**ZIP** **Country** Germany

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2-00

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Christoph	**Family Name or Surname** Walther
Inventor's Signature C. Walth	**Date** 22.03.02
Residence: City Dorfstr DEX **State**	**Country** Germany **Citizenship** Germany
Mailing Address Dorfstr. 35, D-24568 Kattendorf	
City Kattendorf **State**	**ZIP** **Country** Germany

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF THIRD INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	**Family Name or Surname**
Inventor's Signature	**Date**
Residence: City **State**	**Country** **Citizenship**
Mailing Address	
City **State**	**ZIP** **Country**